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February 22, 2023

Via ECF

The Honorable Valerie Figueredo
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: Nonparty Northwell Health's Motions to Modify in *Brian Joseph Gref v. American International Industries, et al.*, No. 1:20-cv-05589-GBD-VF

Dear Judge Figueredo,

K&L Gates LLP represents nonparty Northwell Health, Inc. ("Northwell") with regard to the nonparty subpoenas ("Nonparty Subpoenas")[1] issued to Northwell by defendants American International Industries ("AII") and Whitaker, Clark & Daniels, Inc. ("WCD") (collectively, "Defendants"). The purpose of this letter is to supplement the record in response to the Court's questions and invitation during the February 8, 2023 oral argument on Northwell's Motions to Modify[2] the Nonparty Subpoenas. Accordingly, the Declaration filed contemporaneously with this letter includes a table grouping the supplementary exhibits[3] into the two Rule 45(d)(3) analytical pathways Northwell discussed at the oral argument:

- **Pathway 1**: The Nonparty Subpoenas "require[] disclosure of privileged or other protected matter;" and

- **Pathway 2**: the Nonparty Subpoenas "subject[] [Northwell] to undue burden."[4]

[1] ECF Nos. 265-1 and 268-2.

[2] ECF Nos. 264 and 267.

[3] Please note that the exhibits to the Declaration are not appended in the order in which they are referenced in this letter.

[4] *See* Huff Decl.

Background

In January 2020, Ronald E. Gordon, PhD; Maya Alexandri, JD; Kristin Bevilacqua, MPH; and Jacqueline Moline, MD coauthored and published a peer-reviewed article in the Journal of Occupational and Environmental Medicine: *Mesothelioma Associated With the Use of Cosmetic Talc*.[5] The Article—which "was conducted with approval from the Northwell Health Feinstein Institute for Medical Research" and published "[f]rom the Northwell Health Department of Occupational Medicine and Epidemiology"—summarized the authors' research regarding 33 people with malignant mesothelioma (hereinafter the "Subjects").[6] In accordance with 45 C.F.R. § 164.514,[7] the authors de-identified the Subjects referenced in the Article. With one exception,[8] the Subjects' identities **have never been made public**.

On September 27 and October 14, 2022—after the above-referenced case had been pending for more than two years[9] and the two-day deposition of Dr. Moline had already concluded[10]—Defendants AII and WCD, respectively, served their Nonparty Subpoenas on Northwell.[11] The Nonparty Subpoenas demand that Northwell, for the first time ever, reveal the names of all 33 Subjects. In other words, Defendants ask this Court to require Northwell to re-identify, or unmask, the Subjects in contravention of applicable law[12] and in violation of longstanding public policy shielding the identities of medical research subjects. Yielding to Defendants' demands would enable them—and ultimately the entire asbestos defense bar—to match the Subjects to their otherwise de-identified protected health information in the Article, delve into the Subjects' backgrounds, and feature their protected health information prominently in cross-examinations, briefs, and other papers in litigation

[5] Huff Decl., Ex. A (hereinafter, the "Article").

[6] *Id.*

[7] Huff Decl., Ex. Q (copy of 45 C.F.R. § 164.514 (allowing the use and disclosure of de-identified protected health information)).

[8] This Subject, unlike the other 32, was a party to the litigation in which her identity as a Subject was revealed. *See Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C. July 2021). Unlike here, she executed a HIPAA authorization (through a representative) and provided it to Northwell *in her own case*, allowing Northwell to divulge her identity as one of the Subjects for use *in that same case*. She had also pre-deceased the study. (*See* ECF No. 288, p. 9)

[9] *See* Huff Decl., Ex. T (Order, *Peninsula Pathology Associates*, No. 4:22-mc-1 (E.D. Va. Dec. 23, 2022) (concluding that the information sought by AII's subpoena was only "minimally beneficial," in part because, as here, AII "waited . . . over two years into the *Gref* litigation" to serve the subpoena)).

[10] This case was removed to this Court on July 2, 2020. (ECF No. 1) Dr. Moline was deposed over two days on July 6, 2022 and September 23, 2022. (ECF No. 263, p. 3)

[11] ECF Nos. 265-1 and 268-2.

[12] Huff Decl., Ex. Q (copy of 45 C.F.R. § 164.514(c) ("A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that: (1) . . . The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and (2) . . . The covered entity does not use or disclose the code or other means of record identification for any other purpose, **and does not disclose the mechanism for re-identification**." (emphasis supplied))).

around the country. This is an outcome the Subjects simply did not bargain for in executing any limited-purpose HIPAA authorizations in their individual tort cases.[13] Other courts have recognized this reality, and have jealously protected the anonymity of study participants.[14] Furthermore, expert witnesses on both sides of the asbestos/talc bar—including an expert AII is using in the present case—have testified regarding the importance of maintaining the anonymity of study participants.[15]

Accordingly, Northwell moved to modify the Nonparty Subpoenas "pursuant to Rule 45(d)(3)"[16] to (1) protect the Subjects' privacy, (2) comply with federal law, and (3) independent of these legal obligations, protect its "significant interests" in preserving the integrity of its Human Research Protection Program.[17] Importantly, Northwell did not ask for—and does not seek—a protective order, and neither did Defendants. In any event, a protective order is no solution here. If this Court arms Defendants with the information they seek—even under the auspices of a protective order—they would need only repeat their nonparty subpoena strategy in future litigations, repeatedly wrangling Northwell into cases to which it is not a party in an attempt to repeatedly re-identify these Subjects.[18] The Subject at issue in *Bell*[19] is illustrative. In the few months since the court in that

[13] *See* Huff Decl., Exs. R and S (examples of limited-purpose HIPAA authorizations routinely executed in talc cases; both examples contain sunset clauses).

[14] *See generally In re American Tobacco Co.*, 880 F.2d 1520 (2d Cir. 1989) (upholding extensive redactions "to protect the anonymity of the study participants"); *Deitchman v. ER Squibb*, 740 F.2d 556, 565 (7th. Cir. 1984) ("[W]e do not believe that this case calls for release of identifying information . . . ."); *Lampshire v. Proctor & Gamble Co.*, 94 F.R.D. 58 (GAND 1982) ("The court . . . concludes that the personal identifying information about subjects in the CDC studies . . . should be redacted from all produced documents.").

[15] *See, e.g.*, Huff Decl., Ex. AA (Excerpt from Deposition Transcript of Alan Feingold, M.D., *Weiss v. Albertsons Companies, Inc.*, No. CV2021-090946 (Ariz. Super. Ct. Jan. 24, 2023) (expert for AII in the *Gref* litigation—testifying that subjects in medical and scientific literature are de-identified to protect their privacy rights and because "if people thought they might be identified they might be less willing to participate in that study," and refusing to talk about the *Bell* case without permission from Lathrop, the same firm representing AII in *Gref*)); Ex. BB (Excerpt from Deposition Transcript of Victor Louis Roggli, M.D., *Morrison v. Alfa Laval, Inc.*, No. BC441029 (Cal. Super. Ct. Feb. 3, 2011), 44:25-45:7 ("I also have objection to it because in – personally, because in the 25 years that I've been testifying as an expert in federal and state courts these requests go far beyond anything that have been requested of myself or my colleagues that I'm aware of, and I don't think that they are appropriate investigation into scientific merit or arguments that are made in the scientific literature . . . .")); Ex. CC (Excerpt from Deposition Transcript of Gregory B. Diette, M.D., *Lopez v. Brenntag North America, Inc.*, No. 2017-860222 (M.D.L. Pre-Trial Judge June 19, 2020) (expert witness testifying as to the importance of protecting the identity of the 33 subjects whose medical data is featured in the 2020 peer-reviewed article)); Ex. DD (Excerpt from Deposition Transcript of Theresa Swain Emory, M.D., *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C. Oct. 1, 2020) (Testifying that "revealing anonymized human subjects would jeopardize [Dr. Moline's] medical license")).

[16] ECF No. 264, p. 1; *accord* ECF No. 266, p. 1 (moving "Pursuant to Rule 45(d)(3)"); ECF No. 267, p. 1; and ECF No. 269, p. 1.

[17] *See* ECF No. 266, p. 7, § III.A.; ECF No. 269; and ECF No. 288.

[18] *See generally* Huff Decl., Ex. C (Excerpt from Bloomberg Law asbestos litigation analytics (showing that the same parties to the *Gref* litigation have been involved in hundreds of asbestos cases around the country)); Ex. D (Excerpt from Thomson Reuters asbestos litigation analytics (showing the lawyers for AII and WCD have been involved in hundreds of asbestos cases around the country)).

[19] *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C. July 2021).

case unsealed the identity of that study participant (for reasons that are not applicable in this case), Defendants have repeatedly invoked that Subject's identity in several cases to which she is a stranger.[20]

Oral Argument

The Court heard oral argument on Northwell's motions on February 8, 2023.[21,22] As referenced at the outset of this letter, Northwell presented the Court with two independent legal pathways to protect the Subjects and Northwell. Specifically, under Rule 45(d)(3)(A), the Court "must" modify the Nonparty Subpoenas if it determines that they either require Northwell to disclose "privileged or other protected matter" (Pathway 1), or subject Northwell to undue burden (Pathway 2).[23] Either determination, standing alone, would require modification of the Nonparty Subpoenas. Northwell urged the Court to make both rulings.

Regarding Pathway 1, the Nonparty Subpoenas require disclosure of information that is privileged and protected by the Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46, Subpart A (the "Common Rule"), and the Health Insurance Portability and Accountability Act of 1996's Privacy Rule, 45 C.F.R. Parts 160, 162, and 164 (hereinafter "HIPAA").[24] At oral argument, Northwell emphasized that, regardless of how it received the Subjects' protected health information, Northwell remains subject to both regulations. Moreover, Northwell's Human Research Protection Program Policies and Procedures—which are advertised to the general public—require that Northwell apply the most restrictive regulations to maximize protections for its research participants.[25] In fact, Northwell owes research participants, such as the Subjects, an even greater duty of protection given its determination that informed consent was not required.

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[20] Huff Decl., Ex. B (Consolidated Excerpts from Deposition Transcripts of Dr. Jacqueline Moline (showing that, since the M.D.N.C's *Bell* order, counsel for AII has repeatedly invoked Ms. Bell's identity and PHI in cases to which Ms. Bell is a stranger)).

[21] ECF No. 310.

[22] Defendant WCD offered argument in opposition to Northwell's motion during the December 12, 2022 discovery conference on Defendants' motion to compel the continuation of the deposition of the Plaintiff's expert. (ECF No. 305-1, p. 34; *see also* ECF No. 270 ("Order with respect to 263 Letter Motion to Compel . . . A discovery conference is scheduled for December 12, 2022 at 2:00 p.m. Counsel for the parties are directed to call Judge Figueredo's AT&T conference line at the scheduled time . . . .")).

[23] Fed. R. Civ. P. 45(d)(3)(A).

[24] Although not the main focus of the oral argument, the Subjects' identities and PHI are also protected by IRB standards of privacy and confidentiality, the specific IRB approvals that the authors of the Article secured in advance of their study, *see* Huff Decl., Ex. L (Northwell's IRB approval for the Article), universally accepted norms of ethics in the medical research community, and case law affirming the privacy and confidentiality protections afforded the thirty three people at issue. (*See* ECF Nos. 266, 269, and 288)

[25] Huff Decl., Ex. X (Northwell Health Human Research Protection Program Policies and Procedures, Apr. 20, 2021, publicly available at https://www.northwell.edu/sites/northwell.edu/files/2021-05/HRPP-Policies-and-Procedures-FINAL-2021.pdf).

As a covered entity under HIPAA,[26] Northwell is prohibited from disclosing the Subjects' protected health information.[27] This prohibition applies regardless of whether the information was "created or received by a [covered entity]."[28] Accordingly, the fact that Northwell did not serve as the Subjects' health care provider is immaterial; because Northwell "received" the Subjects' protected health information, it is prohibited from disclosing it under HIPAA unless an exception applies. As relevant here, the definition of "protected health information" (PHI) does not except publicly disclosed information from this prohibition. For example, when a patient voluntarily discloses PHI to a neighbor or even a news reporter, that disclosure does not relieve the patient's doctor (a covered entity) from his or her HIPAA obligations.[29] Indeed, even if the doctor knows that the patient disclosed PHI to the neighbor or reporter, she is still prohibited from disclosing the PHI. Further, if the doctor mistakenly relies on a public disclosure as a basis to release the PHI, he or she can be subject to an enforcement action by the HHS Office of Civil Rights.[30] Thus, the fact that the Subjects may have disclosed certain PHI *in their respective cases* several years ago does not alter the HIPAA analysis for Northwell.[31] Nor does such a disclosure alleviate Northwell's significant interests or those of the Subjects, who are strangers to this case and did not sign up to be featured in every asbestos case in which an expert cites the Article.

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[26] Huff Decl., Ex. N (copy of 45 C.F.R. § 160.103 ("Covered entity means: . . . (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.")). Importantly, no party has challenged Northwell's status as a covered entity; thus, that fact is not in dispute.

[27] Huff Decl., Ex. M (copy of 45 C.F.R. § 164.502(a) ("A covered entity . . . may not use or disclose [PHI], except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.")).

[28] Huff Decl., Ex. N (copy of 45 C.F.R. § 160.103 (emphasis supplied) (defining "protected health information" as "individually identifiable health information," which in turn is defined as "information that is a subset of health information including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to belief the information can be used to identify the individual.").

[29] Moreover, these HIPAA obligations would extend to others in the doctor's practice, even those who did not treat the patient.

[30] *See* Huff Decl., Ex. O (article describing HHS OCR enforcement action against medical practice that released PHI that had previously been disclosed in the media); Ex. P (HHS press release announcing $2.4 HIPAA settlement with medical practice after practice identified an individual as a patient of the practice, even though the patient's status had already been disclosed in the media).

[31] *See* https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html (confirming that "the HIPAA Privacy Rule [generally] prohibit[s] a doctor's office from disclosing an individual's [PHI], including whether they have received a COVID-19 vaccine, to the individual's employer or other parties").

In that regard, and related to the second pathway, the Court should rule that the Nonparty Subpoenas unduly burden Northwell.[32] Irrespective of the application of any particular federal regulation—including, without limitation, the Common Rule and HIPAA—such a ruling is appropriate given Northwell's "significant interests,"[33] especially because Northwell is a nonparty and thus entitled to greater protection from subpoenas.[34] In addition, the timing of the subpoenas, the number of references relied upon by Dr. Moline in her expert report,[35] and the extensive cross examination fodder already available both from the face of the Article[36] and the ruling in *Bell*,[37] collectively render the Subjects' PHI "minimally beneficial" to Defendants.[38,39]

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[32] *See* Fed. R. Civ. P. 26(b)(1) (providing that the burden analysis encompasses the "burden or expense" of the proposed discovery); *Virginia Dep't of Corr. v. Jordan*, 921 F.3d 180, 190 (4th Cir. 2019) ("The text of Rule 26 confirms that "burden" means more than the financial costs of compliance . . . ."); *see also Fappiano v. City of New York*, 640 F. App'x 115, 121 (2d Cir. 2016) (affirming trial court's order incorporating the witnesses "interest in maintaining her privacy" into the burden analysis); Order, *Peninsula Pathology Associates*, No. 4:22-mc-1 (**quashing AII's motion**, imposing sanctions, and explaining "[w]hen assessing the burden to the recipient, courts should consider the financial cost of producing the information as well as 'other cognizable burdens,' such as (1) the impact of production on privacy or confidentiality interests; (2) interests-including business interests- of the recipient and others who might be affected; and (3) whether the subpoena is overbroad and would require 'tailoring' by the nonparty.").

[33] ECF No. 266, § III A.

[34] *See In re Terrorist Attacks on Sept. 11, 2001*, 523 F. Supp. 3d 478, 489 (S.D.N.Y. 2021) (citing *Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998) ("concern for the unwarranted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs" in a Rule 45 inquiry)); *Trellian Pty, Ltd. v. adMarketplace, Inc.*, No. 19CIV5939JPCSLC, 2021 WL 363965, at *2 (S.D.N.Y. Feb. 3, 2021) ("Courts thus afford 'special weight to the burden on non-parties of producing documents to parties involved in litigation,'") (quoting *Travelers Indem. Co. v. Metro. Life Ins. Co.*, 228 F.R.D. 111, 113 (D. Conn. 2005)); *MacNamara v. City of New York*, No. 04CIV.9612(KMK)(JCF), 2006 WL 3298911, at *15 (S.D.N.Y. Nov. 13, 2006) ("However, courts also give special weight to the burden on non-parties of producing documents to parties involved in litigation.").

[35] ECF No. 282-16. The Article is reference number 304 out of the 492 references cited in Dr. Moline's expert report. *Id.*

[36] *Id.* The Article states that "Authors J.M. and R.G. have served as expert witnesses in asbestos litigation, including talc litigation for plaintiffs." *Id.* It further states that "[t]he case series should be understood in the context of its limitations. Data were obtained from medication records and transcripts of depositions, rather than structured, in-person interviews. . . . While deposition testimony is by definition self-report, depositions were given under oath and the potential for recall bias noted would be presented whether patients completed a structured interview or were asked questions during sworn testimony." *Id.*

[37] *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C. July 2021).

[38] Huff Decl., Ex. T (Order, *Peninsula Pathology Associates*, at p. 6 ("In light of these facts, I am persuaded that the additional information sought by subpoena would be minimally beneficial to AII in the *Gref* litigation.")).

[39] *See also* Huff Decl., Ex. Y (Transcript Excerpt from Dec. 16, 2022 oral argument, *Peninsula Pathology Associates* (Lead counsel for AII asserting that "[t]alc litigation started after 2014 with the Gordon/Millette article."); Ex. Z (*Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women*, Ronald E. Gordon, Sean Fitzgerald, James Millette, International Journal of Occupational and Environmental Health, Vol. 20, No. 4 (2014)). *See also* ECF No. 266, § III B.

The Information Requested by the Court at Oral Argument

In discussing Pathway 1, Northwell advised that the authors' application for IRB approval indicated that three of the 33 Subjects were deceased. At the Court's request, the undersigned researched whether those Subjects have asbestos cases that can be located on electronic dockets.[40] In the course of that research, the undersigned identified a fourth individual that was deceased at the time the IRB was approved in March of 2018.

For all four Subjects, the undersigned conducted research to identify the jurisdictions in which they filed their cases. Then, the undersigned checked those jurisdictions to ascertain what information was accessible on the electronic dockets. Where applicable, the undersigned utilized login credentials and paid applicable fees to view available filings, if any. In the case of all four Subjects, this research enabled undersigned to determine that the Subjects were plaintiffs in asbestos cases. For some of the Subjects, the undersigned could view and download docket filings common in civil litigation, which revealed further information about the Subjects' mesothelioma diagnoses. Nevertheless, with the exception of Ms. Bell, **the Subjects' inclusion in the Article has never been made public, and this Court would be the first to order them revealed**. In any event, both legal pathways to protect the Subjects and Northwell remain viable under Rule 45(d)(3) because (1) there is no public disclosure exception to HIPAA, and (2) the Nonparty Subpoenas unduly burden Northwell.

In addition, at oral argument Defendants made certain statements concerning Northwell's Federalwide Assurance ("FWA"). In response, Northwell explained that—as a precondition to receiving federal funding for any of the research it conducts—HHS regulations require it to provide "written assurance" to HHS that it will comply with the Common Rule.[41] And "[t]he [FWA] is the only type of assurance currently accepted and approved by [HHS's Office for Human Research Protections (OHRP)]."[42] Northwell's FWA is a legally binding agreement with HHS,[43] signed by its "signatory official"—Northwell's Executive Vice President of Research—and approved and signed by an HHS approving official.[44] In that agreement, Northwell commits to apply the Common Rule to all research "regardless of the source of support."[45] Thus, once Northwell "checks the box" and elects to extend Common Rule protection to all research, federally funded or otherwise,

[40] We did not dispatch couriers to the various courthouses to attempt to retrieve hard copies of any filings that might exist.

[41] Huff Decl., Ex. F (copy of 45 C.F.R. § 46.103(a)).

[42] *See* https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html.

[43] Huff Decl., Ex. H (HHS Office for Human Research Protections PowerPoint confirming that FWAs "[n]eed to include a 'signatory official' who has the authority to commit the entire institution/organization named in the FWA to **a legally binding agreement**" (emphasis supplied)).

[44] Huff Dec., Ex. G (Northwell's FWA in place at the time of the IRB approval for the Article).

[45] *Id.*

Northwell is legally obliged to do so under penalty of "administrative or legal action."[46] Indeed, Northwell's signatory official attested to the following in executing the FWA:

> *I have read and agree to the Terms of the Federalwide Assurance.*
>
> *I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.*
>
> Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.
>
> All information provided with this Assurance is up-to-date and accurate. **I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action**.[47]

Additionally, Northwell's approved FWA is noted by HHS on its website.[48] Thus, Northwell—like HHS—holds itself out to the public as maintaining that assurance.[49] At oral argument, Northwell indicated that it had documentation related to this point and the Court requested that Northwell supplement its filings with that additional information. As such, the undersigned hereby supplements the record with that information.

Best regards,

/s/ Nathan A. Huff

Nathan A. Huff

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[46] *Id.*

[47] *Id.* (italicized emphasis in original; bold/underline emphasis supplied).

[48] Huff Decl., Ex. I (screen capture of HHS website listing Northwell's FWA, publicly available at https://ohrp.cit.nih.gov/search/FwaDtl.aspx).

[49] Huff Decl., Ex. X (Northwell Health Human Research Protection Program Policies and Procedures, Apr. 20, 2021, publicly available at https://www.northwell.edu/sites/northwell.edu/files/2021-05/HRPP-Policies-and-Procedures-FINAL-2021.pdf).